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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/764,330	01/23/2004	Michael P. Cooke	P1097US10	5772

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GENOMICS INSTITUTE OF THE
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EXAMINER

JUEDES, AMY E

ART UNIT	PAPER NUMBER
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1644

NOTIFICATION DATE	DELIVERY MODE
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11/16/2007

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

IPLegal@gnf.org
jclarke@gnf.org

Office Action Summary

Application No.

10/764,330

Applicant(s)

COOKE ET AL.

Examiner

Amy E. Juedes, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 September 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 12, 14-16, 28-32 and 39 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 12, 14-16, 28-32, and 39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed 9/7/07 in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/14/07 has been entered.

Claims 12, 16, 28-30, and 32 have been amended.

Claims 17-27 and 33-38 have been cancelled.

Claim 39 has been added.

Claims 12, 14-16, 28-32, and 39 are pending and are under examination.

2. The rejection of the claims under 35 U.S.C. 112 second paragraph is withdrawn in view of Applicant's amendment to the claims.

3. The rejection of the claims under 35 U.S.C. 102 is withdrawn in view of Applicant's amendment to the claims. Specifically, da Silva et al. do not teach testing the agent for its ability to inhibit T lymphocyte development at the double positive stage.

4. The rejection of the claims under 35 U.S.C. 112 first paragraph for lack of written description is withdrawn in view of Applicant's amendment to the claims.

5. The following are new grounds of rejection.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 12, 14-16, 28-32, and 39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) Claim 12 is drawn to a method for identifying an agent that inhibits T lymphocyte development. Step a) of the method is assaying IP3KB in the presence of a test agent. This might

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encompass any type of assay. For example, the claims might encompass assaying binding of a test agent to IP3KB in a cell free system or assaying IP3KB biological activity in the presence of a test agent. The claims might even encompass assays that have no relationship to the function of IP3KB, for example assaying the color or viscosity of IP3KB. However, step b) of the claimed method recites identifying an agent that inhibits cellular level of kinase activity of IP3KB. It is unclear how any type of assay, as recited in claim 1, would result in the identification of an agent that inhibits cellular levels of kinase activity. For example, the claims might encompass assaying the binding of a test agent to IP3KB in a cell free system in step a), but this would not necessarily result in the identification of an agent that inhibits the "cellular level of kinase activity" of IP3KB, as recited in step b). Furthermore, step c) of the claimed method recites testing the agent for ability to inhibit T lymphocyte development at the double positive stage, thereby identifying an agent that inhibits the production of mature T lymphocytes. However, the preamble of the claim recites identifying agents that inhibit T lymphocyte development (i.e. any type of T cell development, including, for example, the "development" of a Th1 T cell response). It is unclear how the claimed method could be used to identify agents that inhibit other types of T cell development, other than the production of mature T lymphocytes from double positive T cells.

B) Claim 12 recites the limitation "the cellular level of kinase activity" in line 6. There is insufficient antecedent basis for this limitation in the claim.

C) Claim 14 is indefinite, since it broadens the scope of independent claim 12. Claim 14 recites identifying an agent that inhibits kinase activity of IP3KB. However, claim 12 is already limited to identifying agents that inhibit the "cellular level" of kinase activity of IP3KB.

D) Claims 30 and 32 are indefinite in the recitation of an agent that decreases cellular levels of IP3KB, or inhibits expression of the gene encoding IP3KB. It is unclear how the ability to inhibit cellular levels or gene expression is related to the method of independent claim 12. Typically, a particular type of agent (for example, a small molecule) might inhibit kinase activity, while a distinct class of agent might inhibit gene expression (for example, anti-sense RNA). Are the instant

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claims intended to mean that the identified agents are those that are capable of simultaneously inhibiting both kinase activity of IP3KB and gene expression of IP3KB? If so, it is unclear what type of agent would be capable of inhibiting such diverse processes as enzymatic activity of a protein, as well as transcription of a nucleic acid molecule.

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 12, 14-16, 28-32, and 39 are rejected under 35 U.S.C. 112, first paragraph, as the specification does not contain a written description of the claimed invention, in that the disclosure does not reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention at the time the application was filed. This is a new matter rejection.

The specification and the claims as originally filed do not provide support for the invention as now claimed, specifically:

A) A method comprising identifying agents that inhibit the "cellular level of kinase activity" of IP3KB (Claim 12, and dependant claims 14-16, 28-32, and 39).

B) A method comprising testing an agent for "ability to inhibit T lymphocyte development in the thymus" (Claim 39).

Applicant indicates that support for the new limitations can be found on pages 4 and 5 of the specification.

A review of the specification fails to reveal support for the new limitations.

Regarding A), at pages 4-5, the specification discloses, examining test agents for their ability to modulate a cellular activity of IP3KB, and particularly discloses identifying agents that inhibit IP3KB kinase activity or reduce its cellular level. Thus, while the specification discloses identifying an agent that inhibits the cellular level of IP3KB, or the kinase

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activity of IP3KB, it does not disclose identifying an agent that inhibits the "cellular level" of kinase activity.

Regarding B), at pages 20-21, the specification discloses, testing agents for ability to modulate T lymphocyte development using thymic stromal cells, or administering an agent to an animal that harbors an IP3KB followed by analyzing the thymic cells. However, these specific examples do not provide adequate support for the more broad recitation of testing agents for ability to inhibit T lymphocyte development "in the thymus". For example, the instant claims might encompass injecting an agent into an isolated thymus.


8. No claim is allowed.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy E. Juedes, Ph.D. whose telephone number is 571-272-4471. The examiner can normally be reached on 8am - 5pm, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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11/5/07
G.R. EWOLDT, PH.D.
PRIMARY EXAMINER